REMARKS

Reconsideration of the above application is respectfully requested.

There are six claims pending in this application - claims 1, 11 -12, 17, 25 and 27.

In the Office Action, the Examiner rejected all pending claims under 35 U.S.C. §102(e) as being anticipated by each of U.S. Patent 6,001,876 to Singh ("the '876 patent") and U.S. Patent 6,635,675 to Kranzler ("the '675 patent"). For the reasons that follow, Applicants respectfully traverse this rejection.

The '876 patent does not refer to the use of pregabalin to treat fibromyalgia, but rather refers to the use of pregabalin to treat pain associated with fibromyalgia. Therefore, it does not anticipate any of the rejected claims, all of which are directed to the treatment of fibromyalgia with pregabalin. Pain associated with fibromyalgia is not synonymous with fibromyalgia. The clinical data required by the United States Food and Drug Administration ("FDA") in order to obtain approval for the treatment of fibromyalgia syndrome includes endpoints relating to conditions and symptoms other than pain in contrast to the data required to obtain approval for the indication "pain associated with fibromyalgia". Approval for the treatment of fibromyalgia syndrome requires data that includes endpoints relating to all three of pain, fatigue and function. Data relating to these endpoints for pain, fatigue and function is usually submitted via standard instruments accepted in the art such as, respectively, the Endpoint Mean Pain Score, the Patient's Global Impression of Change (PGIC) and the Fibromyalgia Impact Questionnaire ("FIQ").

The '675 patent does not refer to the use of pregabalin to treat fibromyalgia. Column 7, lines 60 – 65, the section of the '675 patent to which the examiner referred in support of the rejection, merely states that pregabalin is one of several compounds that can be "adjunctively administered with NE 5-HT SNRI compounds" such as milnacipran. It is SNRI compounds, including NE 5-HT SNRI compounds such as milnacipran, that are referred to as being efficacious for the treatment of fibromyalgia, not pregabalin. Nowhere does this reference state that pregabalin can be used to treat fibromyalgia, and nowhere does it state that pregabalin exhibits SNRI activity (or NE 5-HT SNRI activity, a subcategory of SNRI activity), which is the only activity associated with the treatment of fibromyalgia in such reference.

In view of the above comments, Applicants respectfully request that the foregoing rejections under 35 U.S.C. §102(e) be withdrawn.

The Examiner also rejected all pending claims under 35 U.S.C. §103 as being unpatentable over the '876 patent in view of Guymer *et al.*, An Approach to managing

Fibromyalgia, Medicine Today (2002), pp58-59, Vol. 3(12) ("Guymer"). For the reasons that follow, Applicants respectfully traverse this rejection.

In support of the foregoing rejection, the Examiner stated that the '876 patent teaches that pregabalin is an antidepressant and that Guymer teaches the applicability of treatment of fibromyalgia with antidepressants. However, those of skill in the art would recognize that efficacy for the treatment of fibromyalgia syndrome requires more than treatment with an analgesic agent that has been reported to also have antidepressant properties. As indicated above, the clinical data required by the FDA in order to obtain approval for the treatment of fibromyalgia syndrome includes endpoints relating to conditions and symptoms other than pain and depression, specifically, fatigue and function.

In view of the above comments, Applicants respectfully request that the foregoing rejection under 35 U.S.C. §103 be withdrawn.

The Examiner also rejected all pending claims as being unpatentable over the '876 patent on grounds of nonstatutory double patenting. Applicants respectfully traverse this rejection for the same reasons stated above for traversing the rejections based on 35 U.S.C. §§102 and 103, and request that this rejection also be withdrawn.

In view of the above comments, Applicants submit that the inventions of elected claims 1, 11-12, 17, 25 and 27 are directed to patentable subject matter, and they further submit that they are in patentable form. Applicants therefore respectfully request that such claims be allowed to issue.

The Commissioner is authorized to charge any fee required to ensure consideration of this paper to Deposit Account No. 23-0455, and to credit any overpayment to the same.

Respectfully submitted,

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